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PUBLIC MEETING NOTICE:	**CONTROLLED SUBSTANCE COMMITTEE**
DATE AND TIME:	**Wednesday, April 27, 2016 at 9:00 a.m.**
PLACE:	**Buena Vista Conference Center, Buck Library, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720**
APPROVED:	June 22, 2016

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Art Jankowski, VMD, Veterinary Representative
Philip Kim, M.D., Medical Representative
Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Stephen Ruggles, PA-C, PA Representative
Alex Zarow, R.Ph., Pharmacy Representative
Mark Hanna, Public Representative

MEMBERS ABSENT

Luis Garcia, Jr., DPM, Podiatric Representative, Vice President

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David Mangler, Director, Division of Professional Regulation
David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances
LaTonya Brown, Administrative Specialist II
Eileen Kelly, Deputy Attorney General
Samantha Nettesheim, Pharmacist Administrator PMP
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Tejal Patel, PharmD
Hooshang Shanehsaz, R.Ph.
Jeanne Chiquoine

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:04 am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Von Goerres, seconded by Dr. Kremer, to approve the minutes for February 24, 2016. The motion was unanimously carried.

UNFINISHED BUSINESS

Public Hearing – Proposed Revisions to Regulation 4.10.1, 4.10.1.5

Ms. Kelly called the hearing to order and provided the committee an outline of the proposed changes to the regulations. The committee introduced themselves for the record. There was no written or public comment received. Ms. Kelly asked that deliberations on the proposed regulations be added to the next meeting agenda. The hearing concluded.

PRESIDENT'S REPORT

Dr. Kremer informed the committee of a new commission that is being form called the "Drug Overdose Fatality Review Commission". He stated this is an important step in reviewing the drug overdose deaths and diversion in our state. He noted that the commission does not include a pharmacist nor had the Controlled Substance Advisory been contacted for participation. He asked the committee to stay abreast of the findings of this committee as it relates to opioid abuse and over prescribing of opioids. These findings may result requiring assistance from the committee in making changes to current statute and regulations as needed based on their findings.

Dr. Kremer expressed the value of utilizing the PMP. He has experienced at least 2 instances since the last meeting, the PMP provided information and prevent over prescribing. Dr. Kremer urged his colleagues to spread the word for everyone to utilize the PMP for its valuable resources.

NEW BUSINESS

Review and Consideration of Hearing Officer Recommendation – Claudia Cannon

Ms. Kelly reviewed the hearing officer recommendation for the committee. The committee reviewed the hearing officer recommendation and discussed its findings. A motion to amend the hearing officer recommendation increasing suspension from 60 days to 6 months and accepting the remaining recommendations as written was made by Dr. Kremer and seconded by Mr. Von Goerres. The motion carried.

DIRECTOR'S REPORT

Case/Diversion Review

Mr. Dryden informed the committee of 2 robberies that had recently occurred. One presented to be a simple robbery with the suspect brandishing a weapon and getting a bottle of Xanax and a bottle of Oxycodone. There other was more sophisticated where the suspects tied up the pharmacist and two pharmacy technicians up they left with numerous drugs. The Delaware state police continue their investigations in these two robberies. Mr. Dryden went to both locations and completing an inspection which included detailed notes of the incident.

Inspections are continuing, Ms. McCreary is very busy with inspections and Mr. Dryden has been completing Veterinary inspections.

Mr. Dryden reported that the PMP vendor HID is completing upgrades that will make improvements for the user. HID is planning large improvements for overall changes to their database.

The CDC grant was received by the Division of Public Health.

Mr. Dryden presented continuing education on March 19 & 20 for the DEA. There is also a DEA a national drug disposal scheduled for this Saturday April 30th. You can go to the DEA website to locate the locations for drop offs.

Current Events

Public Health Officials Petition FDA for Black Box Warnings and Medication Guides Regarding Serious Risks of Combining Opioids With Benzodiazepines

A petition submitted to Food and Drug Administration (FDA) requests that the agency add a black box warning on all medications in the opioid and benzodiazepine classes to warn prescribers and patients about a reduced margin of safety and increased risk of fatal overdose when these classes of medication are used together. Signed by 41 physicians, including state and local department of health directors, public health officials, and school of medicine faculty, among others, the petition also requests that FDA require medication guides for both classes of medications to specifically warn patients of the potential dangers of combined use of opioids and benzodiazepines. Current warnings "fail to reflect the strong biologic and epidemiological data on risks to patients of respiratory depression and fatal overdose from combining these classes of medications," according to the petition. A black box warning would emphasize to patients the need to discard old or expired medications that could be

combined with new prescriptions for dangerous effects, indicates the petition. The petitioners also state that the warnings would support public education efforts aimed at informing the general public about the epidemic of fatal overdose.

Proposed Federal Bill Would Fund State Development of Standing Orders for Dispensing Opioid Overdose Reversal Drug and Education Programs

Federal legislation that would provide funding to states for the development of standing orders for pharmacies to dispense opioid overdose reversal medication has been introduced by United States Representative Robert J. Dold (R-IL). The bill would also provide state funding for training materials for health care providers to use in educating the public about administering opioid overdose reversal medication. The bill (HR 4586) defines standing order as "a document prepared by a person authorized to prescribe medication that permits another person to acquire, dispense, or administer medication without a person-specific prescription." Also called Lali's Law, the bill would amend the Public Health Service Act.

Prescription Drug Diversion Addressed During DEA Meeting with Drug Supply Chain Industry Leaders

Prescription drug supply chain industry leaders met with United States Drug Enforcement Administration (DEA) Acting Administrator, Chuck Rosenberg, and Deputy Assistant Administrator, Lou Milione, to discuss ways to reduce pharmaceutical diversion while maintaining legitimate commerce and patient access. During the forum held in Washington, DC, attendees were presented with information on federal laws and regulations affecting their industry and had an opportunity to ask questions, share their perspectives, and express concerns about regulatory requirements and current issues, the DEA news release indicates. The forum served to find a balance between making prescription medications available to patients and decreasing addictions, overdoses, and crimes associated with these drugs, explained Rosenberg.

FDA Issues Compliance Policy Guidance Related to Dispensers' Transactions with First Responders

Food and Drug Administration (FDA) issued a new guidance for industry indicating the agency does not intend to take action against a dispenser who transfers ownership of a product directly to a first responder without providing product tracing information to the first responder, as required by sections 582(c)(1)(A)(ii)-(iv) and (d)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act. FDA does not intend to take action provided that certain conditions are met, as outlined in the Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy Guidance for Industry. The compliance policy guidance indicates that requirements for transactions with first responders include the following: (1) the dispenser captures and maintains the product tracing information for such transactions for not less than six years after the transaction; and (2) the dispenser provides such product tracing information to the first responder or secretary, if requested, not less than two business days after receiving the request or in such other reasonable time as determined by the secretary, based on the circumstances of the request..

DEA to Hold Next National Prescription Drug Take-Back Day in April

Drug Enforcement Administration (DEA) has announced another opportunity for consumers to dispose of unneeded and expired prescription drugs during the 11th DEA National Prescription Drug Take-Back Day, which will be held April 30, 2016. On this day, from 10 AM to 2 PM, thousands of collection sites will be available across the country to accept unneeded prescription drugs, including controlled substances, for safe and legal disposal. To date, DEA's Take-Back Day initiative has collected a combined total of more than 5.5 million pounds (over 2,750 tons) of unneeded medications, helping to prevent diversion, misuse, and abuse of the drugs

CDC Issues Guideline for Prescribing Opioids for Chronic Pain

Centers for Disease Control and Prevention (CDC) published 12 recommendations about prescribing opioid pain medication for primary care clinicians who treat patients 18 years or older with chronic pain in outpatient settings. The recommendations are grouped into three areas and address:

1. determining when to initiate or continue opioids for chronic pain;
2. opioid selection, dosage, duration, follow-up, and discontinuation; and

3. assessing risk and addressing harms of opioid use.

The purpose of the guideline is to strengthen communication about the risks and benefits of opioid therapy between clinicians and patients, improve the safety and effectiveness of pain treatment, and reduce the risks related to long-term opioid therapy, including opioid use disorder, overdose, and death.

New York Law Mandates Electronic Prescribing for Controlled Substances and Non-Controlled Substances

Prescribers in the state of New York must issue electronic prescriptions directly to a pharmacy according to a new law. All prescriptions must be transmitted in electronic format, except for certain limited circumstances, effective March 27, 2016, under the Internet System for Tracking Over-Prescribing (I-STOP) Act. The regulations require prescribers and pharmacists to have a secure system for electronic transmission of the prescription from computer to computer in order to protect the confidentiality of patient information, notes the Office of the Professions (OP) advisory notice. New York is the first state to mandate electronic prescribing and enforce penalties, such as fines and imprisonment, for physicians who do not comply.

President Obama Announces Administration's Actions to Combat Drug Abuse at National Rx Summit

President Barack Obama attended the National Rx Drug Abuse and Heroin Summit in Atlanta, GA, on March 29, 2016, and announced actions his Administration is taking to further expand access to treatment, prevent overdose deaths, and increase community prevention strategies. The expanded initiatives will include public and private sector actions taken to address the epidemic, building on efforts announced in October 2015.

HHS Proposes Increasing Buprenorphine Patient Limit for Medication-Assisted Treatment

With the goal of expanding access to medication-assisted treatment (MAT), United States Department of Health and Human Services (HHS) has proposed a rule that would permit qualified physicians to prescribe buprenorphine, the opioid use disorder treatment medication, to as many as 200 patients. Under current regulations, physicians who are certified to prescribe buprenorphine for MAT can only prescribe up to 30 patients initially and after one year can request authorization to prescribe up to a maximum of 100 patients. Substance Abuse and Mental Health Services Administration Principal Deputy Administrator Kana Enomoto states "there are long patient waiting lists for prescribers who have reached the 100 patient limit." Buprenorphine is a Food and Drug Administration (FDA)-approved drug used as part of MAT, a comprehensive way to address the recovery needs of individuals that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

Recommended Legislative Changes from the Board of Pharmacy – Syringe Law §4762

Ms. Kelly provided a draft of proposed changes from the Board of Pharmacy. The committee reviewed these changes. Ms. Kelly will provide the committee a formal draft of the proposed changes to §4762 during its next meeting.

Dextromethorphan (DMX) Legislative HB329

The legislation would require the cashier to verify the age of anyone who appears to be under the age of 25 to ensure that the purchaser is at least 18 years of age. It would not require the product to be kept behind the counter.

House Resolution Concurrent 68

A copy was provided to the committee for informational purposes.

COMMITTEE REPORTS

Medical Examiner's Report

No report.

DEA Report

No report

Substance Abuse Report

No Report
Law Enforcement Report
No Report
Regulatory Committee Report
No Report
Legislative Committee Report
No Report

COMMITTEE CORRESPONDENCE
"Benzodiazepine Prescribing Patterns and Deaths from Drug Overdose among Us Veterans"
CDC - "Guidelines Prescribing Opioids"
News Journal article from the CDC entitled - "Doctors told not to prescribe opiates for Chronic Pain"

OTHER BUSINESS BEFORE THE BOARD
None

PUBLIC COMMENTS
Mr. David Mangler addressed the committee regarding HID, PMP as well as the CDC grant. Conversation has begun regarding the use of funding from this grant to integrate the DHIN information with PMP information. Discussions have also occurred regarding the possible utilization of a third party vendor to assist with in depth analysis of Medicaid recipient health record data along with PMP data for dangerous prescribing patterns. This would provide targeted educational opportunities. Staff support was also requested to assist with meeting the demands of these initiatives. Staff support needed would be a Pharmacist, Analyst and Administrative Specialist to assist the current PMP Administrator.

Mr. Mangler commented on the current proposed "Safe Opioid Prescribing" Regulations completed by Secretary of State, Jeffrey Bullock. Mr. Mangler provided the committee an outline of the changes.

Ms. Tejal Patel, PharmD expressed concern for the age requirement of a minimum of 18 years in the Photo ID law. She also expressed concern for the use of professional discretion of the pharmacist for dispensing of syringes. She would like the committee to review these laws an open the discussion for change.

Ms. Jeanne Chiquoine, Cancer Society expressed concern for the age restriction of 18 years for controlled substances. This could cause unintended hardship for those patients that are under 18 years of age that pick up their own medications. She would ask the committee to reconsider this restriction.

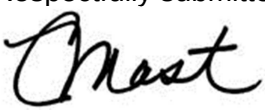
Mr. Shanehsaz, R.Ph. agreed with Ms. Chiquoine regarding the age restriction and the unintended consequence it may cause. He also asked the committee to review the syringe law changes that the Board of Pharmacy had provided. These changes would provide better patient care in the pharmacy setting.

EXECUTIVE SESSION
None

NEXT SCHEDULED MEETING
The next regular meeting will be held on June 22, 2016 at 9:00 am at the Buena Vista Conference Center, Buck Library.

ADJOURNMENT
A motion was made by Mr. Von Goerres, seconded by Dr. Kim, to adjourn the meeting at 10:06 am. The motion carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Office of Controlled Substances